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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,557	09/03/2003	Dennis A. Grahm	STAN-186CON	6413
24353	7590	01/21/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVE SUITE 200 EAST PALO ALTO, CA 94303			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,557

Applicant(s)

GRAHN ET AL.

Examiner

Roy D. Gibson

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/16 & 3/12/04 *RDR*
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 3739

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,673,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely broader in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3739

Claim 1 recites the limitation "said cold conditions" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "said mammal" in line 3 and claim 12 recites the limitation "said cold conditions" in line 9. There is insufficient antecedent basis for these limitations in the claim.

Claim 21 recites the limitation "said mammal" in line 3 and claim 12 recites the limitation "said cold conditions" in line 9. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6-7, 10-12, 14-16, 19-20 and 22-25 and 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Borders (6,149,674).

As to claims 1, 2, 4 and 11, Borders discloses the method essentially as claimed wherein the method comprises:

(a) detecting a requirement for thermal energy input in a human mammal;

Art Unit: 3739

(b) contacting a surface of a portion of said mammal in response to the presence of said requirement with a warm temperature medium under negative pressure conditions for a period of time sufficient to introduce thermal energy into the core body of said mammal; and

(c) maintaining a substantially constant core body temperature of said mammal under cold conditions (not defined) by maintaining the contact with said warm temperature medium; wherein said requirement is detected by detecting the presence of a thermoregulatory error in said mammal; and wherein said method further comprises at least partially enclosing said portion of said mammal in a sealed enclosure to produce an enclosed portion of said mammal (Figures 1, 3 and 4 and col. 2, lines 42-57, col. 3, line 14-col. 4, line 55 and col. 7, lines 11-63).

As to claims 6 and 7, Borders discloses the portion of the mammal is a limb consisting of an arm or a leg.

As to claims 10, 12, 14-16 and 19-20, Borders discloses the method is applied to a patient during a surgical procedure which inherently can be at least about 60 or minutes or longer under cold conditions (cold is undefined and could be the cool climate of a surgical theater).

As to claims 22-25 and 28-29, Borders discloses a device comprising:

(a) a means for detecting a need for thermal energy by measuring the patient's (mammal) temperature with a sensor (64);

(b) an enclosure (sleeve # 20) for enclosing an arm or a leg of the patient;

Art Unit: 3739

(c) a negative pressure generator (86); and

(d) a warmer (22 and Figures 1, 3 and 4 and col. 2, lines 42-57, col. 3, line 14-col. 4, line 55, col. 5, lines 46-59 and col. 7, lines 11-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 17, 18, 21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borders.

As to claims 8, 17, 21 and 27, Borders fails to disclose the specific range of the vacuum applied to the sleeve, but it would have been obvious to one of ordinary skill in the art to determine the required vacuum and, since the range is so broad (-20 to - 80 mm Hg), thus revealing the non-criticality of the negative pressure, to determine the appropriate value or range by simple experimentation.

As to claims 9 and 18 and 21, Borders fails to disclose the specific range of the temperature of the medium or warmer (22) to be within 44-48°C. However, the examiner maintains it would have been obvious to a skillful artisan to determine the required temperature by simple experimentation and that the temperature range would typically fall within the claimed range.

Art Unit: 3739

Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (5,683,438). Grahn discloses an apparatus and method for core warming of mammals experiencing hypothermia which is obvious over claims 22 –29, because it would have been obvious to measure the initial temperature of the limb of the patient as the means to detect a requirement for thermal energy (col. 2, line 40-col. 3, line 11 and col. 3, line 24-col. 4, line 38).

Allowable Subject Matter

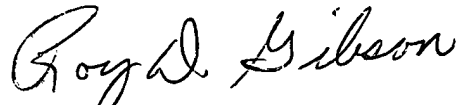
Claims 3, 5 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson
Primary Examiner
Art Unit 3739

January 12, 2005